UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER
WEST, JEFFREY R

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>25 June 2007</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,8-10,12-14 and 84-138* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,8-10,12-14 and 84-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>25 June 2007</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☒ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

2. Claims 87, 106, 109, 114-116, 124, 128, and 135-138 are objected to because of the following informalities:

In claim 87, line 1, to avoid problems of antecedent basis, "clinical graphical" should be ---clinician graphical---.

In claim 106, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 109, line 1, to avoid problems of antecedent basis, "clinical graphical" should be ---clinician graphical---.

In claim 114, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 115, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 116, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 124, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 128, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 135, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 136, line 2, to avoid problems of antecedent basis, "control input" should be ---control inputs---.

In claim 137, line 2, to avoid problems of antecedent basis, "said test" should be ---said at least one test---.

In claim 138, line 2, to avoid problems of antecedent basis, "said test" should be ---said at least one test---.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 88, 89, 110, 111, 126, 127, 134, 137, and 138 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out

and distinctly claim the subject matter which applicant regards as the invention.

Claims 88 and 89 are considered to be vague and indefinite because they refer

to "said preconfigured software instructions" while there is no previous mention of

any "preconfigured software instructions". Therefore, it is unclear to one having

ordinary skill in the art as to what "said preconfigured software instructions" refer.

Claims 110 and 111 are considered to be vague and indefinite because they

refer to "said software instructions" while there is no previous mention of any

"software instructions". Therefore, it is unclear to one having ordinary skill in the art

as to what "said software instructions" refer.

Claims 126 and 127 are considered to be vague and indefinite because they

refer to "said software instructions" while there is no previous mention of any

"software instructions". Therefore, it is unclear to one having ordinary skill in the art

as to what "said software instructions" refer and whether or not "said software

instructions" refer to the previously presented "program code instructions".

Claim 134 is considered to be vague and indefinite because it refers to "said

program code instructions" while there is no previous mention of any "program code

instructions". Therefore, it is unclear to one having ordinary skill in the art as to what

"said program code instructions" refer.

Claims 137 and 138 are considered to be vague and indefinite because they

refer to "said software instructions" and "said testing computer" while there is no

previous mention of any "software instructions" or "testing computer". Therefore, it is

unclear to one having ordinary skill in the art as to what "said software instructions"

and "said testing computer" refer.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 5, 8, 9, 84, 90-95, 99, 106, 112-116, 119, 121, 124, 128, 131-133,

135, and 136 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S.

Patent No. 6,334,072 to Leysieffer.

With respect to claim 1, Leysieffer discloses a system for performing a test on a

hearing prosthesis implanted in a recipient (column 8, lines 24-26) comprising: a

testing computer (column 6, lines 49-52) comprising a processor configured to

process software instructions and to output signals in response to said processed

software instructions (column 7, lines 38-52); a prosthesis interface configured to

transfer said outputted signals from said testing computer to the hearing prosthesis

interfaced with said testing computer (column 6, lines 45-64); and a recipient

interface configured to receive a control input from the recipient of the hearing and to

cause said processor to perform said test in response to said control input (column

6, line 65 to column 7, line 7).

With respect to claim 99, Leysieffer discloses a method for performing a test on a hearing prosthesis implanted in a recipient (column 8, lines 24-26) with a recipient-controlled system operationally coupled to the hearing prosthesis (column 6, lines 45-64), the method comprising: receiving, at a recipient interface of the system, test control inputs provided by the recipient (column 6, line 65 to column 7, line 7); and performing, by the system, a test on the hearing prosthesis in response to said test recipient-provided control inputs (column 6, line 65 to column 7, line 7).

With respect to claim 119, Leysieffer discloses a computer readable medium comprising program code instructions (column 6, lines 39-42) which, when executed by a recipient-controlled processor-based system, cause the processor to perform a test method on a hearing prosthesis (column 7, lines 38-52) implanted in a recipient and operationally coupled to the system (column 8, lines 24-26), the method comprising: receiving, at a recipient interface of the system, test control inputs provided by the recipient; and performing the test on the hearing prosthesis in response to said test control inputs (column 6, line 65 to column 7, line 7).

With respect to claim 131, Leysieffer discloses a system for performing at least one test on a hearing prosthesis implanted in a recipient (column 8, lines 24-26) with a recipient-controlled system operationally coupled to the hearing prosthesis (column 6, lines 45-64) comprising: means for receiving, at a recipient interface of the system, test control inputs provide by the recipient; and means for performing, by the system, said at least one test on the hearing prosthesis in response to said test control inputs (column 6, line 65 to column 7, line 7).

With respect to claim 5, Leysieffer discloses that said testing computer is further configured to store result data of said test for later assessment (column 3, lines 53-58).

With respect to claims 8, 121, and 132, Leysieffer discloses that said testing computer is further configured to store result data of said test on a storage means/meduim (column 3, lines 53-58).

With respect to claims 9 and 133, Leysieffer discloses that said storage means is disposed in the hearing prosthesis (column 6, lines 39-45).

With respect to claims 84, 106, 124, and 135, Leysieffer discloses that said recipient interface comprises an input interface configured to receive said control input and cause a processor to received said control input (column 7, lines 4-8).

With respect to claims 90 and 112, Leysieffer discloses that said input interface comprises a recipient graphical user interface (column 6, lines 51-52).

With respect to claims 91 and 113, Leysieffer discloses that said input interface comprises a custom user input device (column 6, lines 51-52).

With respect to claims 92, 114, 128, and 136, Leysieffer discloses that said input interface is configured to cause said processor to respond to said control input (column 7, lines 4-8)

With respect to claims 93 and 115, Leysieffer discloses that said input interface is configured to cause said processor to commence said test upon receiving said control input (column 7, lines 4-8).

With respect to claims 94 and 116, Leysieffer discloses that said input interface is configured to cause said processor to perform and control the tests and therefore the input interface is configured to cause the processor to start and stop/discontinue said test upon receiving said control input (column 7, lines 4-8 line 47 to column 8, line 2).

With respect to claim 95, Leysieffer discloses that said prosthesis interface is an external port on said testing computer (column 6, lines 45-64 and Figure 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10, 85-89, 96, 100-103, 107-111, 120, and 125-127, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer in view of U.S. Patent No. 5,626,629 to Faltys et al.

As noted above, the invention of Leysieffer teaches many of the features of the claimed invention and while the invention of Leysieffer does teach a computer that process software instructions and output signals to perform testing of a hearing prosthesis (column 7, lines 38-52), Leysieffer does not explicitly indicate that the computer is located at a clinic for use by the recipient when visiting the clinic.

Leysieffer also does not specifically describe a corresponding programming system/method using the clinician computer.

Further, while the invention of Leysieffer does teach allowing real-time (i.e. immediate) visualization of results or storing data for later analysis (Leysieffer; column 3, lines 53-58), Leysieffer does not explicitly indicate that the storage for later analysis is a portable magnetic disk for use by a clinician.

Faltys teaches programming of a speech processor for an implantable cochlear stimulator with a personal computer (column 5, lines 20-26) connected to the cochlear device via a cable (column 6, lines 5-6) and located at a clinic for use by the recipient when visiting the clinic (column 4, lines 26-33 and column 13, lines 61-64) for immediate presentation of results to a clinician (column 7, lines 42-65).

Faltys further teaches that the clinician computer comprises means for programming software instructions of the cochlear device (column 5, lines 20-30) using a graphical user interface (column 8, lines 19-23) prior to performing a test (column 10, lines 26-53) or in response to/modified by results from the test (column 7, lines 42-65 and column 8, lines 14-23) wherein the clinician computer is configured to cause a processor to initiate said test such that said testing computer performs said test upon said initiation by processing software instruction and communicating with the hearing prosthesis (column 7, lines 42-65 and column 8, lines 14-23).

Faltys also teaches that the programming is based on patient specific data (column 11, lines 34-39 and column 12, lines 13-39) stored in a portable magnetic disk (column 22, lines 35-44).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer to explicitly indicate that the computer is located at a clinic for use by the recipient when visiting the clinic, and the corresponding system/method using the clinician computer, as taught by Faltys, because, as suggested by Faltys, the combination would have improved the system of Leysieffer by providing the apparatus at a location with experts and specialists, such as audiologists, that have the experience and knowledge to properly adjust the hearing system of Leysieffer, thereby ensuring the maximum amount of functionality of the system (column 7, line 42 to column 8, line 13).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer to explicitly indicate that the storage for later analysis is a portable magnetic disk for use by a clinician, as taught by Faltys, because, as suggested by Faltys and known by one having ordinary skill in the art, magnetic disks are common methods for transporting data and therefore the combination would have provided increased efficiency of the system of Leysieffer by allowing the user to transport specific patient data (column 11, lines 34-39, column 12, lines 13-39, and column 22, lines 35-44) while improving the apparatus of Leysieffer by providing the data to specialists, such as audiologists, that have the experience and knowledge to properly adjust the hearing system of Leysieffer, thereby ensuring the

maximum amount of functionality of the system (column 7, line 42 to column 8, line 13).

9. Claims 97, 98, 117, 118, 129, 130, 137, and 138, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer in view of Faltys et al. and further in view of U.S. Patent No. 6,115,478 to Schneider.

As noted above, the invention of Leysieffer and Faltys teaches many of the features of the claimed invention and while the invention of Leysieffer and Faltys does teach a local testing computer configured to process software instructions and perform a test as well as a clinician computer configured to process software instructions and perform a test by communicating with the hearing prosthesis, the combination does not specify that the clinician computer controls the testing computer.

Schneider teaches an apparatus for and method of programming a digital hearing prosthesis comprising a local system and computer and a remote system and computer wherein the remote system controls the local system to initiate synthesizing signals for transmission to the hearing prosthesis (column 9, lines 50-58).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer and Faltys to specify that the clinician computer controls the testing computer, as taught by Schneider, because, as suggested by Schneider, the combination would have improved the system of Leysieffer and Faltys by allowing

the clinician to perform a desired process (i.e. test) by causing the local system to

perform the process, thereby reducing the burden of the user to physically provide

the hearing prosthesis to the clinician computer, but rather use the existing local

system (column 9, lines 50-58).

10. Claims 12-14, 122, 123, and 134 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Leysieffer in view of U.S. Patent No. 5,909,497 to Alexandrescu.

As noted above, the invention of Leysieffer teaches many of the features of the

claimed invention and while the invention of Leysieffer does teach a computer that

process software instructions and output signals to perform testing of a hearing

prosthesis (column 7, lines 38-52) as well as allowing real-time (i.e. immediate)

visualization of results or storing data for later analysis (column 3, lines 53-58),

Leysieffer does not explicitly indicate that the computer is located remote from a

clinician at a recipient's home with the ability to transmit data to a clinician.

Alexandrescu teaches a programmable hearing aid instrument and programming

method thereof including a computer interface (column 4, lines 4-19) located at a

location remote from a clinician of the recipient at the recipient's home (column 8,

lines 19-33) wherein the computer interface is operable to obtain software

instructions from the hearing prosthesis (column 5, lines 37-49) as well as deliver

data specific to the hearing prosthesis electronically to a computer of a

clinician/specialist of the recipient (column 5, lines 17-20) using the Internet (column

7, line 66 to column 8, line 4).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer to explicitly indicate that the computer is located remote from a clinician at a recipient's home with the ability to transmit data to a clinician, as taught by Alexandrescu, because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

11. Claims 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer in view of Faltys and further in view of U.S. Patent No. 5,909,497 to Alexandrescu.

As noted above, the invention of Leysieffer and Faltys teaches many of the features of the claimed invention and while the invention of Leysieffer and Faltys does teach a computer that process software instructions and output signals to perform testing of a hearing prosthesis (column 7, lines 38-52) as well as allowing real-time (i.e. immediate) visualization of results or storing data for later analysis (column 3, lines 53-58) and a clinician computer for analyzing results, the combination does not explicitly indicate that the computer is located remote from the clinician at a recipient's home with the ability to transmit data to a clinician.

Alexandrescu teaches a programmable hearing aid instrument and programming method thereof including a computer interface (column 4, lines 4-19) located at a location remote from a clinician of the recipient at the recipient's home (column 8, lines 19-33) wherein the computer interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49) as well as deliver data specific to the hearing prosthesis electronically to a computer of a clinician/specialist of the recipient (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4).

It would have been obvious to one having ordinary skill in the art to modify the invention of Leysieffer and Faltys to explicitly indicate that the computer is located remote from the clinician at a recipient's home with the ability to transmit data to a clinician, as taught by Alexandrescu, because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

Response to Arguments

12. Applicant's arguments with respect to claims 1, 5, 8-10, 12-14, and 84-138 have been considered but are moot in view of the new ground(s) of rejection.

The following arguments, however, are noted.

Applicant argues:

> As noted above, Leysieffer describes testing, evaluating, programming the
> implanted device. Also as noted above, Leysieffer describes a patient only in the
> context of being able to adjust hearing aid functions using a remote control. No
> where does Leysieffer teach or suggest system for performing a test comprising
> an interface configured to receive a control input from the recipient, as claimed in
> Applicants' claim 1. Thus, Applicants respectfully assert that Leysieffer neither
> discloses nor suggests Applicants' invention as recited in independent claim 1.
> Accordingly, Applicants respectfully request that the rejection of independent
> claim 1 be reconsidered, and that it be withdrawn.

The Examiner asserts that Leysieffer discloses a data storage for storing

patient/recipient-specific parameters that are obtained from the recipient though a

recipient interface comprising an external unit (column 6, lines 39-52):

> The signal processing components 40, 50, 80 are controlled by a
> microcontroller 100 (uC) with the associated data storage (S) via a unidirectional
> or bidirectional data bus 15. In the storage area S, patient-specific audiological
> adaptation parameters can be filed. This individual programmable data is sent to
> the controller 100 via the data bus 15 by a telemetry unit 110 (T). This telemetry
> unit 110 communicates wirelessly through the closed skin shown at 57, for
> example as shown in FIG. 1, via an inductive coil coupling, and bidirectionally
> with an external telemetry interface 111 (T1). The telemetry interface 111 is in
> bidirectional communication with a display and/or evaluation unit 112 which can
> advantageously be a computer (PC) with the corresponding processing and
> display software.

The Examiner also asserts that Leysieffer discloses the parameters of the

measurement/testing functions, which are programmed through the external unit

(see above), as well as commands for causing the processor to perform the

measurements/testing functions are controlled by a control input received through

the recipient interface including the external unit (column 7, lines 2-8):

The parameters of the measurement functions of the measurement system
13 can likewise be selected or changed via the data bus 15 by the controller 100.
The request for a measurement function takes place via control commands of the
external unit 112 via the telemetry interface 111. These control commands
trigger the corresponding actions of the implant-side controller 100.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to

Applicant's disclosure:

U.S. Patent No. 6,879,693 to Miller et al. teaches a method and system for

external assessment of hearing aids that include implanted actuators.

U.S. Patent Application Publication No. 2002/0176584 to Kates teaches an

apparatus and methods for hearing aid performance measurement, fitting, and

initialization.

U.S. Patent No. 6,366,863 to Bye et al. teaches a portable hearing-related

analysis system.

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus and method of

programming a digital hearing aid.

U.S. Patent No. 4,847,617 to Silvian teaches a high speed digital telemetry

system for implantable devices.

U.S. Patent No. 5,609,616 to Schulman et al. teaches a physician's testing

system and method for testing an implantable cochlear stimulator.

EP Patent Application Publication No. 0 124 930 to Crosby et al. teaches a

cochlear implant system for an auditory prosthesis.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
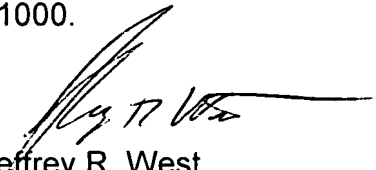
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (571)272-2226. The examiner can normally be reached on Monday through Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571)272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-

272-1000.

Jeffrey R. West
Primary Examiner
Art Unit – 2857

September 17, 2007